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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,884	11/02/2001	Cy A. Stein	0575/63293/JPW/BJA	5706

7590 12/04/2003  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, NY 10036

EXAMINER
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SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/002,884	<b>Applicant(s)</b> STEIN ET AL.	
	<b>Examiner</b> J. Douglas Schultz	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

In response to applicant's indication that the restriction requirement mailed October 3, 2003 was written to comply with 35 U.S.C. § 371 lack of unity, when in fact it was a U.S. national filing, the following corrective action is taken to bring the restriction requirement into compliance with U.S. restriction practice. The previously mailed requirement for restriction is hereby vacated, and the period for reply of 1 MONTH set in said Office Action is restarted to begin with the mailing date of this letter.

#### ***Election/Restrictions***

- I. Claims 1-10, 22, 24-32, and 34-39, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 2 and the oligonucleotide of SEQ ID NO: 5, including methods of making and using said compound and pharmaceutical compositions thereof, classified for example in class 514, subclass 44.
- II. Claims 1-10, 23, 24-32, and 34-39, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 2 and the oligonucleotide of SEQ ID NO: 6, including methods of making and using said compound and pharmaceutical compositions thereof, classified for example in class 514, subclass 44.
- III. Claims 11-22, 24-31, and 33-39, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 1 and the oligonucleotide of SEQ ID NO: 5, including methods of making and using said compound and pharmaceutical compositions thereof, classified for example in class 514, subclass 44.

- IV. Claims 11-21, 23-31, and 33-39, drawn to the molecular complex comprising the polypeptide of SEQ ID NO: 1 and the oligonucleotide of SEQ ID NO: 6, including methods of making and using said compound and pharmaceutical compositions thereof, classified for example in class 514, subclass 44.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the nucleotide and amino acid sequences recited in claims 1-39 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Claim 1-39 specifically claims SEQ ID NOS 1, 2, 5, and 6, which represent antisense oligonucleotides and membrane permeable carrier proteins. Applicant has claimed the use of each protein with each oligo, in complex. Each complex is considered to be unrelated to the other complexes, since each complex claimed is structurally and functionally independent and distinct for the following reasons: each complex has sequences that are unique nucleotide sequence and not shared with any other complex, each complex targets a different and specific region of its target gene, and each antisense, upon binding to its target, is expected to functionally modulate (increase or decrease) the expression of its target gene and to varying degree, because it is well known in the art that the activity of an antisense sequence is dependent upon its sequence. Furthermore, a search of more than one (1) of the complexes claimed in the above listed claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the

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search and corresponding examination of more than one sequence complexes. In view of the foregoing, one (1) such complex is considered to be a reasonable number of compounds for examination. Accordingly, applicants are required to elect one (1) group outlined above, each of which contains one oligo/protein complex.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

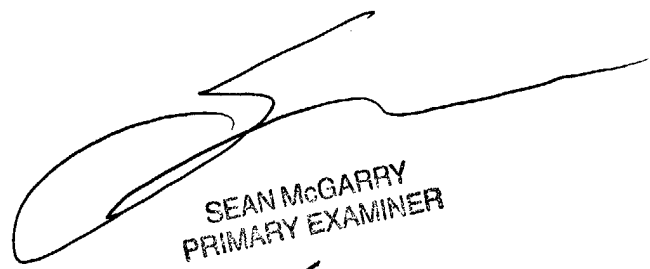
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD



SEAN MCGARRY  
PRIMARY EXAMINER  
1635